

REMARKS

This Response is submitted in reply to the Office Action mailed April 23, 2004 ("the Action"). Claims 1-59 are pending in the application. Claims 11, 36, 44, 46 and 50-57 have been withdrawn from consideration by the Examiner as "being drawn to a nonelected invention and/or species." The Examiner agrees that Applicants timely traversed the restriction. Applicants respectfully request reconsideration of the withdrawal of at least Claims 50-54 and 57 as they recite special technical features corresponding to pending dependent claims such as Claim 38, Claims 58 and 59, as will be discussed further below.

The pending claims stand rejected as being anticipated by US Patent Application Publication No. 2002/0076056 ("Pavlakos") and/or obvious over Pavlakos alone or combined with a secondary reference and/or over U.S. Patent No. 4,024,499 to Bosscher in view of U.S. Patent No. 3,808,354 to Feezor. Applicants respectfully disagree.

I. The Objection to Claim 32

Applicants have amended Claim 32 to obviate the objection noted by the Examiner. Accordingly, Applicants respectfully request that this objection be withdrawn.

II. A Brief Summary of Some Embodiments of the Present Invention

Some embodiments of the present invention can be configured to provide substantially real-time interaction between the test and remote "control site" via an Internet system where a clinician at the remote site can be interactively involved with the testing at the local site during the test. In some embodiments, the instant systems can be configured as multi-purpose testing systems that can perform a plurality of tests, with different test codes, typically 2 or 3 different procedures with as many as 10-12 different test codes, *i.e.*, current procedural terminology (CPT and/or ANSI) test codes. The test codes may be established by the AMA (see www.ama-assn.org/ama/pub/category/3112.htm) Examples of such procedures include, but are not limited to, bone conduction, speech audiometry, tympanometry and/or otoacoustic emissions. The systems can be configured to provide a substantially real-time interactive testing environment where the remote control site can

"observe" the testing environment and/or control the test. In some embodiments, the test is actually performed at the local patient site while being controlled in substantially real-time from the remote site using a relatively small portable controller and testing/measurement devices, such as a signal generator and the like. This interaction during the testing allows customized patient-specific test procedures and/or evaluations, which may provide more clinic-like analysis rather than "canned" testing procedures. Also, in some embodiments, the web pages can be refreshed and the web pages can be served from the local patient site to the parent site to facilitate the interaction.

III. The Prior Art Rejections

Claims 1 and 2 stand rejected under 35 USC §102(e) as being anticipated by Pavlakos. As noted by the Action, Pavlakos proposes an Internet-based audiometric testing system. However, Pavlakos proposes a system whereby software gathers output data and personal information data of the person and presents the data in a "predetermined audiological test report data form" so that a remote site receives the test data in a test report from "for review by a person certified in audiometric testing." Pavlakos Abstract and col. 2, ¶ 28. Notably, there appears to be no interactive communication between the remote site and patient site during the test. Indeed, Pavlakos proposes that the remote server can transmit "with verified signature" one of "acceptable" or "unacceptable" to the test site, similar to a "pass" or "fail" analysis. Pavlakos ¶ 28. Pavlakos proposes a single test type, namely, industrial audiological testing.

Pavlakos states that screens shown in Figures 6a, 6b and 7 may be "edit accessible" by the audiometric technician (Pavlakos ¶ 35). However, these "editable" screens appear to merely allow the technician to rate the transmitted test results as "normal" or not and to characterize the test and/or provide a medical referral or a recommendation of hearing protection; these editable screens do not provide for real-time interaction during the test between the test and remote sites. In summary, Pavlakos appears to be similar to prior technology that proposes to "store and forward" or "gather then send" testing systems. *See, e.g.,* Pavlakos ¶13.

In view of the foregoing, Applicants respectfully submit that Claims 1 and 2 are not anticipated by Pavlakos.

Claim 1 recites in-part:

interactively relaying information between the patient located at the local site and a clinician located at the test administration site during said administering step so that the clinician can evaluate the patient's response to the hearing assessment signals, the test administration site being remote from the local site.

Thus, Claim 1 clearly recites interactive relaying of information during the administration of the hearing evaluation test. As discussed above, Applicants submit that Pavlakos does not disclose or suggest such interactive relaying of information.

Claims 1-10, 12-35, 37, and 47-49 stand rejected as being obvious over Bosscher in view of Feezor (Action, p. 3). However, Bosscher merely proposes a local stand-alone system that is controlled on-site by a clinician. Feezor proposes an "automatic self-administered hearing test" and the "degree of sound intensity of the signal is controlled by the examinee" (col. 5, lines 1-5). The Action opines that it would have been obvious to one of ordinary skill of the art to "modify the method of Bosscher with the computer network of Feezor to conduct mass hearing tests using a small number of clinicians."

However, assuming for argument that one would have combined these references, notably, even combined, Bosscher and Feezor fail to teach or suggest a testing system where the local testing equipment is controlled by a remote site during the test and/or an interactive test as recited in independent Claim 1 (and hence its dependent claims, Claims 2-30), independent Claim 31 (and its dependent claims, Claims 32-37) and independent Claim 47 (and its dependent claims, Claims 48-49). Rather, properly combined, Feezor and Bosscher merely describe a "store and forward" type of testing evaluation whereby the test is performed locally and then forwarded to a central site for later review. Feezor states that "[m]eans are provided for the rapid and accurate accumulation and computation of the hearing test results at a separate remotely located data processing center for subsequent analysis" (Feezor, col. 40, lines 35-40, emphasis added). Further, a supervisor at the test site can control the local testing

and can "invalidate an individual hearing test...in the event of malfunction, unexpected noise, etc..." (Feezor, col. 37, lines 19-22 and Figure 29). Feezor fails to disclose a remotely controlled test or an interactive evaluation between the remote and local sites.

Exemplary claims, including portions of the independent claims are restated here for ease of discussion. Claim 1 recites in-part:

interactively relaying information between the patient located at the local site and a clinician located at the test administration site during said administering step so that the clinician can evaluate the patient's response to the hearing assessment signals, the test administration site being remote from the local site.

Claim 31 recites in part:

controlling the output of the hearing assessment signals which are relayed to the patient during said transmitting step at a local site from a test administration site which is remote from the patient site, wherein said controlling step is carried out such that a clinician at the test administration site determines which hearing assessment signals of said generating step are relayed locally to the patient.

Claim 47 recites in-part:

wherein the hearing evaluation device is configured to receive commands from a remote site through said processor over the computer network during the hearing evaluation to select and/or adjust the tones generated by the tone generator.

As is clear from the above cited portions of independent Claims 1, 31 and 47, embodiments of the present invention reflected in these claims provide interaction between local and remote site during test administration. Such an interactive system is neither disclosed nor suggested by Feezor and/or Bosscher. Accordingly, Applicants respectfully submit that the claimed subject matter is non-obvious and patentable over the cited references. Applicants submit that the dependent claims are likewise patentable for at least the patentability of their base claims.

While each of the dependent claims is patentable as depending from a patentable base claim, Applicants submit that certain of the dependent claims are separately patentable over the cited references. For example, Claim 3 recites "adjusting the output of a hearing assessment signal during said administering step based on the response of the patient and a

command sent from the remote site." Claims 6-9 recite additional remote operational features. Applicants submit that neither Bosscher nor Feezor disclose or suggest the subject matter recited in Claim 3 or Claims 6-9. Accordingly, Applicants submit that Claim 3 and Claims 6-9 are separately patentable for at least these additional reasons.

In addition, regarding Claims 5, 29 and 35, the Action states (at page 4) that although the references fail to specifically recite meeting predetermined test (CPT and/or ANSI) standards, "it would have been obvious to one of ordinary skill in the art to comply with ANSI standards in view of the universal scientific /medical desire for accurate testing and diagnosis." Applicants agree that there may have been a desire for an accurate test, but until the instant invention, there was no enabling disclosure on how one might operate a remote interactive Internet-based test in a way that could reliably control audio signals sufficient to comply with predetermine standards (i.e., CPT and/or ANSI requirements), particularly where remote control of the test is employed and signal distortion transmitted over the communications media can undesirably vary. Indeed, in some embodiments, the present invention can provide a system that can economically perform several different (insurance) coded hearing tests (potentially 10-12 different test codes) that may allow increased access to persons that, in the past, may not have had access to the variety of tests made available by embodiments of the present invention. Accordingly, Applicants submit that Claims 5, 29 and 35 are separately patentable over the cited references for at least these additional reasons.

The Action also states at p. 5 regarding Claims 21-25 that although the cited references fail to teach computer implemented scheduling it would have been obvious to one of skill in the art to use a computer for scheduling "since scheduling software for medical applications is well known in the art."

Applicants agree that scheduling is well known for many medical applications. However, Feezor, Bosscher and Pavlakos all teach away from the use of computer scheduling with a remote site for their hearing evaluation procedures as they perform the test and forward for "subsequent analysis." Hence there is simply no motivation or need to provide computer scheduling with the remote site for hearing evaluations as claimed. Accordingly, Applicants respectfully submit that Claims 21-25 are separately patentable over the cited art for at least

these additional reasons.

The Action states that it would have been obvious in view of Pavlakos to "reload web pages to provide the most current data" (p. 5 of the Action) with respect to Claims 38-43, 58 and 59 because "it is well known to reload or refresh web pages" and since Pavlakos proposes a remote web server, a "local server" is a "mere reversal of parts". Applicants again respectfully disagree. As noted above, the instant invention can be configured to provide dynamic interactive communication between the local test site and the remote clinician site during the testing procedure and the cited claims recite features associated with the substantially real-time communication during the test. One of skill in the art would not have found it obvious to control the test at the patient site during the test as claimed based on the teachings of Pavlakos that merely proposes a "store and forward" type of industry testing analysis (*see also*, Figure 1 of Pavlakos with a local client and remote server). Further, in contrast to Pavlakos, the claimed subject matter is directed to a local web server and remote client and facilitates the remote control of the local test during the test. Applicants direct the Examiner's attention below, with portions of the affected claims restated for discussion. One of skill in the art would not find the subject matter recited in Claims 38-43, 58 and 59 obvious in view of Pavlakos. In addition, Applicants respectfully request that the Examiner provide a reference that supports the conclusion that the claimed client/ web server operation and configuration recited in these claims is "well known" as it is improper to base a rejection on unspecified general knowledge. *In re Sang Su Lee*, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002).

Claim 38 recites in-part:

serving web pages from a web server associated with a diagnostic hearing test device at the local patient site to a web client which indicate a status of the diagnostic hearing test;
receiving requests from the web client which provide parameters for performing the diagnostic hearing test during the diagnostic hearing test; and
controlling operation of the diagnostic test device based on the parameters of the received request from the web client so as to provide control of the diagnostic hearing test.

Claim 58 recites in-part:

hosting a socket connection at a web server located at a local patient site for the transfer of data associated with a diagnostic hearing test device at the local patient site to a remote client which indicates a status of the diagnostic hearing test;

establishing test parameters of the hearing test device over the hosted socket connection;

controlling operation of the diagnostic test device over the hosted socket connection based on the parameters received from the client over the hosted socket connection so as to provide control of the diagnostic hearing test during the hearing test;

receiving results associated with the diagnostic hearing test at the client over the hosted connection; and

wherein the steps of establishing, controlling and receiving are carried out so as to in sufficient number and variation of frequency and sound level intensity to provide enough information to the client to allow a diagnostic hearing evaluation to be performed by a clinician according to predetermined standards.

Claim 59 recites in-part:

pinging the web server to determine if the web server is available; and
requesting status of the diagnostic hearing test device from the web server if
pinging the web server indicates that the web server is available.

Accordingly, Applicants submit that Claims 38-43, 58 and 59 are separately patentable for at least these additional reasons.

The Action (pp. 5-6) goes on to reject Claim 45 as being obvious over Pavlakos as applied to Claims 1 and 38 and also in view of Feezor et al. The Action concedes that Pavlakos does not disclose measuring transient or distortion product emission levels. However, the Action states that Feezor provides measurements of ambient noise (70) and distortion measurements (71), concluding that "it would have been obvious to modify the method of Pavlakos with the measurements of Feezor" to conduct "the most accurate and efficient hearing tests". Applicants again respectfully disagree.

First, Applicants note that the Feezor patent issued in 1974. The Pavlakos patent publication was filed in 2002. However, despite the alleged motivation to conduct "the most accurate and efficient hearing tests", Pavlakos is notably silent on these measurements.

Further, even combined, Feezor and Pavlakos fail to provide an enabling teaching of an interactive test as recited in Claim 45 whereby the noise and/or distortion can be measured in substantially real-time and monitored by the remote site so that *in situ* test decisions can be made by the remote site. Accordingly, Applicants submit that Claim 45 is separately patentable for at least these additional reasons.

IV. Claims 46-50 and 57

As noted above Claims 46-50 and 57 share special technical features similar to pending and non-withdrawn claims, such as, for example, Claims 38, 58 and 59. These claims are also patentable over the cited references and Applicants request that these claims remain pending in the application.

Claim 46 recites:

A hearing evaluation device, comprising:
a web server;
a diagnostic test device operably associated with the web server and configured so as to be controlled by the web server; and
wherein the web server is further configured to serve web pages to a web client which indicate a status of a diagnostic hearing test, receive requests from the web client which provide parameters for performing the diagnostic hearing test, and control operation of the diagnostic test device based on the parameters of the received request from the web client.

Claim 50 recites:

A method of controlling a hearing test, the method comprising the steps of:
serving web pages from a web server associated with a hearing test device to a web client which indicate a status of the hearing test;
receiving requests from the web client which provide parameters for performing the hearing test; and
controlling operation of the hearing test device based on the parameters of the received request from the web client so as to provide control of the hearing test.

Claim 57 recites:

A hearing evaluation device, comprising:
a web server;

a diagnostic test device operably associated with the web server and configured so as to be controlled by the web server; and wherein the web server is further configured to host socket connections to a web client that provide data that indicates a status of a diagnostic hearing test, receive requests from the web client that provides parameters for performing the diagnostic hearing test, and control operation of the diagnostic test device based on the parameters of the received request from the web client.

V. New Claims 60-67

Applicants have added new Claims 60-67 to form a more complete claim set. The subject matter is supported by the figures and specification (*see, e.g.*, pp. 22-23 and Figures 3-6). Consideration and entry is respectfully requested. It is noted that Claim 64 is directed to the non-elected species.

VI. Supplemental Information Disclosure Statement ("IDS")

A supplemental IDS was filed on May 13, 2004. Applicants respectfully request that the Examiner return a copy of initialed Form PTO 1449 pursuant to the MPEP.

VII. Replacement Drawing Sheets


Formal replacement drawings have been submitted concurrently herewith with Sheet 9 (Figure 9) amended to correct box 220 as indicated in a Request For Approval of Drawing Corrections submitted on April 19, 2002.

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VIII. Conclusion

Applicants submit that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted, _____

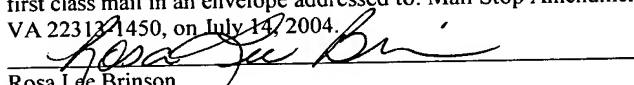


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